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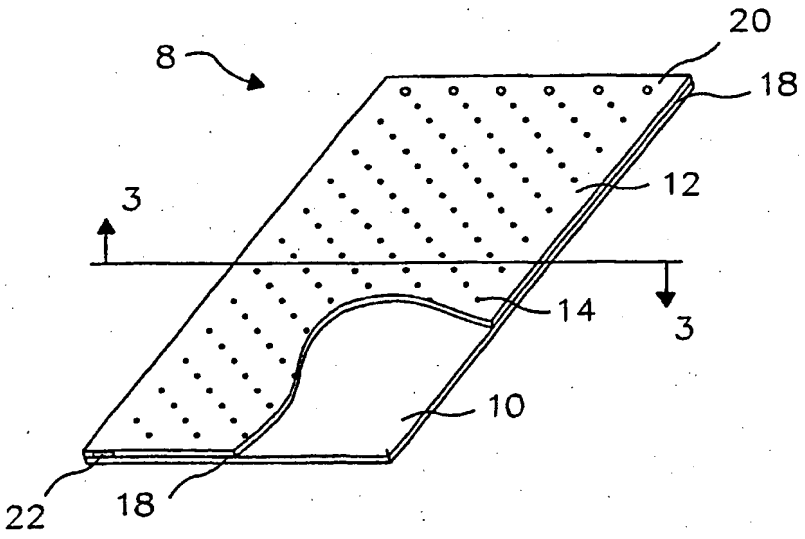

(57) Abstract

A disposable thermoregulation system to maintain normal temperature in an intraoperative and/or postoperative patient, the system comprising multiple layers (10, 12) of a flexible, fluid impermeable material joined together to form a plurality of passageways (24) for transporting therethrough a continuous flow of a least one temperature controlling fluid thereby providing a source of conductive heat to the patient; and a reflective surface (16) positioned on at least one of the multiple layers (10, 12) to reflect escaping radiant heat back to the patient. Furthermore, the pressurized nature of the fluid within the passageways causes the system to conform to the patient's body.

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THERMOREGULATION SYSTEMS

TECHNICAL FIELD

The present invention relates in general to thermoregulation systems and in particular to warming systems that maintain a patient's body heat by reducing heat loss due to evaporation and radiation while providing conductive transfer of heat to the patient.

BACKGROUND OF THE INVENTION

Hypothermia is considered the clinical state of sub-normal temperature when the body is unable to generate sufficient heat to efficiently maintain functions. Inadvertent hypothermia occurs when individuals are exposed to conditions of an operating room and can affect up to 60% of surgical patients. The operating room environment which includes a low room temperature, a lightly clad patient and anesthetics which interfere with thermoregulation are all major contributors to intraoperative hypothermia. Heat loss occurs through various mechanisms including:

i) radiation which is the loss of heat outward from a warm body to a cooler environment without direct contact;

ii) convection which is the loss of heat to air currents dependent upon the temperature gradient between the body and the ambient air;

iii) conduction which is the loss of heat from a warmer surface through direct contact with a cooler one; and

iv) evaporation which is transfer of heat on changing from a liquid to a gas via perspiration or respiration.

Of these, radiation and convection account for the majority of a body's heat loss especially during the first hour of surgery. The patient is brought into a cold operating room, separated from most of his or her clothing and bedding, and anesthetized. The patient is forced to adapt to a cold, dry breathing system and then subjected to wet and cold skin prep solutions. All of these factors contribute to a rapid fall in a patient's temperature.

The adverse effects of hypothermia in a surgical patient relate primarily to shivering, oxygen consumption, cardiovascular and central nervous system changes, and metabolism.

Postanesthetic shivering is a common complication which may cause serious cardiorespiratory complications, as well as patient discomfort and disruption of delicate surgical repair. Shivering also causes dramatic increases in muscle metabolism, increases in oxygen consumption with the concomitant demand for increased cardiac output and ventilation.

Hypothermia is not a benign event. It contributes to prolonged stays in the postanesthesia care unit, thereby increasing costs. It often compromises many of the patient's systems, any or all of which may have been compromised previously by preoperative disease or intraoperative events, such as blood loss, anesthetic agents and the surgical procedure.

Maintaining normothermia should be the goal for every patient during surgery to decrease the chance of surgical wound infection, shorten hospitalization time, and decrease the incidence of morbid cardiac events. With this goal in mind, several methods have been introduced to reduce the complications of hypothermia intraoperative and postoperative.

A passive method of draping with a reflective blanket is disclosed in U. S. Patent No. 4,765,323 wherein a surgical drape having a reflective surface is placed over the patient to prevent loss of heat by reflecting a patient's radiant heat and reducing convective heat loss. When the patient is draped, heat losses by radiation and convection are reduced and the rate of heat loss may decrease but thermoregulatory control may still not occur because no additional heat is provided to warm the patient.

Active warming methods have been used to apply exogenous heat to the body. Superficial warming blankets such as that disclosed in U.S. Patent No. 5,125,238 use warmed forced-air directed at the patient positioned under the warming blanket. However, this method does not prevent heat loss due to radiation. Furthermore, moisture that is emitted from the surface of the body can be turned to vapor by air convection and when this occurs heat is extracted from the body.

Accordingly, there is a need for a patient warming system that can maintain normothermia by providing an additional source of heat to the patient without the disadvantages of heat loss through evaporation or radiation.

SUMMARY OF THE INVENTION

Accordingly, it is a principal object of the present invention to provide a patient warming system that decreases radiant and convective heat loss and warms the patient by conductive heat transfer.

Yet another object of the present invention is to provide a patient warming system with a radiant barrier to reflect a significant amount of a patient's escaping radiant heat back to the patient.

Still another object of the present invention is to provide a patient warming system that reduces the rate of exchange of water molecules immediately adjacent to the skin.

A further object of the present invention is to provide a patient warming system that completely encircles the patient's body and may adhere to itself for a secure closure.

A still further object of the present invention is to provide a patient warming system that at least partially encloses the body of a patient in the form of a drape, leggings, hood, fitted harness for joints, such as knee, shoulder, elbow or heel, and/or bag type structure.

Another object of the present invention is to provide different sources of thermal energy that when combined can actively warm the patient.

Yet another object of the present invention is to provide increased surface area in the warming system for additional surface contact with the patient to conductively transfer heat to the patient.

These and additional objects are provided by a patient thermoregulation system comprising multiple layers of a flexible, fluid impermeable material joined together to form a plurality of passageways for transporting therethrough a continuous flow of at least one temperature controlling fluid thereby providing a source of conductive heat to the patient; and a reflective surface positioned on at least one of the layers to reflect escaping radiant heat back to the patient.

Specifically, the patient warming system comprises:

at least a first and second layer of flexible, fluid impermeable polymeric material joined at their perimeters to form at least one enclosed interior chamber, the first layer positioned adjacent to the patient;

a reflective surface positioned on at least the second layer to reflect thermal radiation back to the patient;

at least one fluid flow passageway within the interior chamber defined by securing the first and second layer together at a plurality of connecting points within their perimeters; and

at least one input and output port connected to the interior chamber for continuous transport of a temperature controlling fluid through at least one fluid flow passageway.

The first layer and/or second layer may further comprise a reflective surface positioned within the interior chamber to reduce heat loss due to radiation.

Additionally, this embodiment may provide for the second layer to extend beyond the first layer a sufficient amount to provide a sufficient area for positioning a reclining patient directly on the reflective second layer to be covered with a portion of the blanket system that comprises both the first and second layer. Reduced to the basics, the patient is placed on a portion of the blanket that is non-inflatable but reflective and then covered with a portion of the blanket that is both inflatable and reflective. The second layer is secured to the first layer to enclose the patient therein.

The plurality of connecting points which join the first and second layer should be in a sufficient quantity to prevent ballooning of the warming system during inflation and also accommodate transport or circulation of the temperature controlling fluid through the fluid flow passageways at a rate that allows for optimum transfer of heat to the patient. The points of connection between the layers may form many suitable configurations such as a plurality of longitudinal passageways that merge to provide access to input and output ports or a staggering of the connecting points to provide flow distribution throughout the entire warming system without the concomitant increased thickness due to inflation.

The input port or ports adapted for introducing a continuous stream of a temperature controlling fluid should be positioned at a location in the warming system for maximum flow of fluid without restriction or blockage by the enclosed or partially enclosed patient. The output port or ports may be connected to a fluid supply source for recirculation of the introduced moving fluid. In the alternative, the fluid may be released to the ambient surroundings with the proviso that the released and exiting fluid is directed away from contact with the patient thereby reducing heat loss due to convection.

The warming system may further comprise means for fastening that allows the

warming system to completely encircle a body part of the patient and be securely maintained in this position while in use.

In another embodiment used for cooling a patient, the fluid being transported through the interior chamber system may be a cool gas or liquid and the reflective surface is positioned to reflect ambient heat away from the patient.

In yet another embodiment, a three layer construction is employed to form the warming system comprising a first layer adjacent to the patient, a second outer layer and a middle layer positioned between the first and second layer. In this embodiment, the middle layer and second layer form a plurality of air passages for inflation by transporting a warm gas therethrough. Additionally, the middle layer is attached to the first layer to form a plurality of passages for transporting a warm liquid therethrough. The air passages formed by joining the second layer and middle layer are defined by attaching the layers on their perimeters and in a pattern of connecting points. Preferably, the second and middle layer have less connecting points then the amount of connecting points between the middle and first layer. By increasing the connection points between the first and middle layer with a decrease in the spatial intervals between connecting points there is provided additional surface contact by the first layer and the patient. As a warm liquid is introduced into the liquid passageways there is more surface contact of the first layer with the patient and this allows for a greater transference of thermal heat from the warm flowing liquid to the patient. It should be noted that additional surface contact of the first layer with the patient is provided by inflation of the air passageways which causes increased pressure on the liquid passageways with a concomitant custom fit to the contours of the patient's body.

This embodiment further comprises a reflective layer for reflecting thermal radiation escaping from the patient's body back to the patient. Preferably, the reflective layer is positioned on at least the second layer.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be clearly understood, it will now be described, by way of example, with reference to the accompanying drawings, wherein:

FIG. 1 illustrates a perspective view of an embodiment of the present invention in which the

second or outer layer is partially taken away to show the first or inner layer;

FIG. 2 illustrates an enlarged, cross-sectional view of a peripheral edge of the warming system showing the relationship of separate layers of the present invention;

FIG. 3 shows an enlarged, cross-sectional elevational view of fluid flow passageways formed by securing points within the interior chamber as taken along line 3-3 of FIG. 1;

FIG. 4 depicts an enlarged, cross-sectional elevational view of an input port of the present invention;

FIG. 5 shows a perspective view of a bag style embodiment of the present invention;

FIG. 6 illustrates an end view of a drape embodiment encircling the patient in an non-inflated mode;

FIG. 7 illustrates the drape embodiment of FIG. 6 in an inflated mode;

FIG. 8 shows an enlarged, cross-sectional view of a peripheral edge showing a metallized, reflective coating on opposites side of the first layer;

FIG. 9 illustrates an enlarged, cross-sectional view of a peripheral edge of the present invention showing a reflective surface on both the first and second layer positioned to reflect emitted radiant heat back to the patient;

FIG. 10 shows a perspective view of the drape embodiment of the present invention with an extended second layer having an adhesive strip thereon;

FIG. 11 shows a method of wrapping the patient in a drape of the present invention;

FIG. 12 illustrates an enlarged, cross-sectional view showing the relationship of the separate layers to the interior chamber in one embodiment;

FIG. 13 illustrates an enlarged, cross-sectional elevational view of fluid flow passageways formed by securing points within the first and second interior chamber of a three layer system;

FIG. 14 illustrates an embodiment of the present invention having resistive heating elements;

FIG. 15 illustrates an embodiment having fluid tubes for carrying warming or cooling liquids;

FIG. 16 shows a perspective view of a baby bunting having a warming system of the present invention;

FIG. 17 illustrates a warming drape as it is removed from packaging; and

FIG. 18 illustrates the warming drape as it covers the patient and secured onto itself during use.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, FIGS. **1, 2,** and **3** illustrate one embodiment of a patient warming drape **8** of the present invention having a generally rectangular shape. The warming drape has a first layer **10** which is an inner layer that is positioned adjacent to the patient's body and a second layer **12** which acts essentially as an outer layer. The first layer **10** is secured to the second layer **12** at their perimeters along peripheral edges **18** forming an interior chamber **13** (shown in FIG. **12**) which is further sectioned into fluid flow passageways **24** by securing the first layer **10** to the second layer **12** at connecting points **14**. The interior chamber is inflated by connecting a temperature controlling fluid source to input port **22** and the fluid is transported or circulated through the fluid flow passageways for release at an output port **20**. The second layer **12** has an interior and exterior side with the exterior side having a reflective surface **16** positioned to reflect any escaping thermal radiation back to the patient. Also, the reflecting layer confines and reduces heat loss from the warm fluid as it is propelled or circulated through the fluid flow passageways.

While in use, the warming blanket is inflated, and a substantial portion of the first layer surface makes direct contact with the patient.

The first and second layer, **10** and **12** respectively, may be fabricated from any flexible, fluid impermeable material such as a polymeric film which is sufficiently puncture and tear resistant. The film material may be a thermoplastic material such as poly(ethylene terephthalate) known by the trade name Mylar, polystyrene polyvinyl chloride, low or medium density polyethylene, polypropylene, polyester, nylon, polybutylene, or vinyl of sufficiently thin thickness to be flexible. The first layer **10** preferably has a thickness of from about 0.01 mil to about 2 mil and the second layer has a thickness of at least that of the first layer, and preferably, of a greater thickness.

At least the second layer **12** includes, at least on the exterior surface, a thin layer of metallic or other reflective materials such as aluminum, silver, gold, copper, chromium or alloys thereof or other metal of sufficient density to reflect a significant portion of any thermal radiation incident thereon. The metallic reflective layer **16**, as shown in FIG. **2**, may be a metallic foil sheet bonded to the second layer or more typically is a deposit coating of the metal or alloy which is very thin but sufficiently dense to reflect the above mentioned

radiation. Such a coating may typically be provided as by sputtering from a heated element in a vacuum or by other methods.

The density of the metallic coating will determine the level of reflectivity and conductivity of the surface coating, and as such, the particular end use will determine the density of the coating. The present invention also contemplates embodiments wherein the metallic coating must be sufficient to reflect radiant heat but not sufficient to conduct current. This may be necessary in operating arenas wherein the warming system is needed but the system must be electrically nonconductive. Generally, the density of an aluminum metallic coating in the nonconducting embodiment may be from about 250 Å to about 500 Å.

In another preferred embodiment the density of the metallic surface must be sufficient to reflect radiating heat waves and conduct heat through the surface. As such, the density of the metallic coating should be sufficient to reflect from about 90% to about 95% of the radiant heat and the coating may approach 50,000 Å.

It is also possible, but not absolutely necessary, to provide a thin, transparent top coat of organic material over the metallic layer to prevent oxidation of the metallic layer which would reduce the efficiency of the reflective layer.

The first layer **10** is secured to the second layer **12** along the peripheral edges **18** of the layers thereby forming an interior chamber. Securing may be made by many appropriate fastening techniques, including, but not limited to sonic welding, laser welding, adhesive attachment, heat sealing, and a combination thereof.

The first and second layers are further secured together by a plurality of connecting points **14**, as shown in FIG. **3**, dispersed within the perimeters of the joined layers. These connecting points may be placed randomly, arranged in even or offset rows throughout the warming blanket or a combination thereof. The first layer may be attached to the second layer at the connection points by any of the above disclosed fastening techniques. The connecting points are of a sufficient size to insure attachment but also provide sufficient space in the fluid flow passageways for easy transport of the temperature controlling fluid through the interior chamber. The securing points may be placed sufficiently close together to provide an even distribution of fluid flow through the passageways without causing a ballooning effect in the drape structure. Furthermore, the points may be randomly placed or as a continuous seam running substantially the length of the blanket system. Preferably, the

connection points are spaced at about 1" to about 6" intervals, and more preferably 1" to 4" intervals.

The temperature controlling fluid, whether it is gas or liquid, is introduced into the warming system at input port **22**. The fluid input port may be placed at any desired location including, but not limited to a site along the sealed peripheral edges **18** as shown in FIG. **1**. In the alternative, the input port may be located completely within either the first or second layer. Preferably, the input port is positioned in a location wherein the fluid flow is not constricted or retarded by the patient's body.

An appropriate fitting acting as the input port may be constructed of any material having sufficient rigidity to snugly receive a fluid nozzle but flexible enough to easily adapt around the patient. Preferably, the material is cardboard or a polymeric material.

Any suitable input port fitting may be employed that may be adapted to fit most hose nozzles of standard warming or cooling units. As shown in Figure **4**, rim **40** of the input port **22** may be constructed of a cellulose or polymeric type material which provides structural support to the input port. Rim **40** may further comprises an elastomeric fitting **42** that is conformable to most standard size fluid hose nozzles. Output port **20** whether one or several may also be constructed accordingly.

The external temperature controlling fluid supply, whether warm or cool fluid, is a separate heating or cooling unit and forms no part of the invention. Typically, warm air supplies are transportable low pressure units, similar to a hair dryer construction or the like and have a controllable volume flow rate which can provide constant or variable flow rates. Furthermore, the temperature of the air can be controlled at a constant or variable temperatures. The air supply is connected to the input port **22** via means of a flexible hose. Output ports may also be connected to the heating unit to provide recirculation of the warm air.

It should be noted that additional types of heating and cooling units may be incorporated into the present invention including but not limited to flexible tubing that circulates hot or cold liquid and resistive heating elements as shown in FIGS. **14** and **15**, respectively. Flexible tubing **11** and resistive heating elements **19** that are devices well known in the art may be fabricated directly into the first layer or by adhesion to the first layer **10** such that the connection points joining the first and second layer do not interfere with either

the transfer of liquid through the tubing or electrical connection of the resistive heating elements. Preferably, the flexible tubing **11** or resistive heating elements **15** are preferably positioned in an elongated placement extending the length of the blanket system. The first and second layer are joined to each other along their peripheral edges and at connecting points within the peripheral edges. The connecting points may be placed randomly, arranged in even or offset rows, or a combination thereof throughout the warming blanket. Preferably, the connecting points are elongated seams **17** that extend substantially the entire of the blanket thereby forming elongated air passages. The elongated air-passages are left unbonded at both ends of the blanket to allow air passage from the input port **22** through the tubes to the output port.

Figure **5** shows another embodiment of the present invention wherein the warming system is constructed in a bag-like style wherein a elongated rectangle drape is folded providing a fold edge **30** and then secured along the peripheral edges **32** by any of the fastening means explained above. The first layer **10** forms the interior of the bag-like structure and directly contacts the patient. The reflection layer may be positioned on the first and/or second layer, and preferably, on the second layer. The input port **22** may be placed at any location on the structure, and preferably at the fold edge **30** thereby providing easy transport and/or circulation of the warm fluid through the interior chamber to output ports **20**. Output ports **20** may be attached to the heating units for recirculation of the warm fluid. It should be noted that if a fluid, such as warm air, is not recirculated then it should be released in a direction away from the patient's body to reduce convective heat loss. The bag style may be constructed in several different sizes so that when inflated it snugly fits around the patient. This embodiment may be used as a warming bunting and can further include a hood for premature babies to maintain normothermia.

Figures **6** and **7** show the warming system of the present invention when in use. Initially, the warming drape encircles the patient and in some areas will not make full contact with the patient's body. However, upon inflation the first layer **10** is expanded inwardly towards the patient.

The present invention which incorporates a metallized, reflective layer positioned on the second layer is a major advantage over the prior art. Warming systems that are currently available subject the body to convective air flow which in turn causes the evaporation of

surface moisture with the concomitant loss of additional body heat. In the present invention, radiation of heat may occur under the first layer in the open spaces that do not directly contact the skin surface, but advantageously the reflective surface reflects the radiant energy back to the patient with a minimal reduction of heat because of the immediate transference back to the patient. Additionally, loss of thermal heat from the flowing fluid is reduced by the reflective layers.

It is further contemplated in this warming drape embodiment that the second layer be of heavier grade or greater thickness of a thermoplastic material than that of the first layer. It is believed that if the first layer **10** is thinner and has some elastomeric properties that upon inflation the first layer **10** will expand inwardly to a greater degree than the second layer **12** expands outwardly. This inward expansion provides more contact of the first layer with the patient thereby providing larger contact surface areas and exposure to the warmth of the flowing fluid through the warming system.

Figure **8** illustrates another embodiment of the present invention and shows first layer **10** having metallized surfaces **16** on both the interior and exterior side. It is believed that by providing a metallized surface in contact with the warm fluid moving through the fluid flow passageways a conducting route and/or surface is created and conduction of heat through the first layer to the patient may be enhanced. Of course this transfer will only occur if the temperature of the warming fluid is greater than the body temperature of the patient. Any material having good thermal conductivity may be used as the metallized surface coating on the interior side of the first layer, including but not limited to aluminum, gold, silver, and copper.

Figure **9** shows another embodiment of the present invention wherein the first layer **10** has a reflective surface on the exterior layer and the second layer **12** has a reflective surface **16** that is positioned on the interior side facing into the interior chamber. This reflective surface will reflect any radiant energy that has escaped through the first layer **10** and will also confine and reduce heat loss of the warm fluid as it is propelled or circulated through the fluid flow passageways. Additionally, it is believed free convection within the interior chamber is reduced. Free convection results because of internal fluid circulation between opposites surfaces of the interior chamber. The second layer **12** of the system is exposed to the cold temperatures of the operating room while the first layer **10** is in contact

with the patient's warm body. This difference in temperature exposures can cause an internal circulation or free convention due to a temperature gradient. Free convention may expose the first layer and subsequently the patient to cooler temperatures. Thus understood, the reflective surface **16** on the interior side of the second layer **12** may reduce heat loss through the surface with a concomitant reduction in free convection within the interior chamber.

Figure **10** illustrates another embodiment of the present invention showing a warming drape wherein the second or outer layer **12** extends beyond the first or inner layer **10**. In this embodiment, the warming system comprises a second layer having a reflective surface that extends beyond the warming drape that comprises both a first and second layer. The first and second layer are secured to each other along the peripheral edges of the first layer and secured within its peripheral edges by a plurality of connecting points as described above. The second layer extends a sufficient distance to provide ample surface area in which to positioned the body of a patient directly thereon. The first and second layer portion of the drape is then placed over the body of the patient and can be secured to the extended second layer **12** which further provides a means of fastening and securing the warming drape onto itself after encircling the patient. Positioned on the interior side **15** of second layer **12** is a adhesive material which upon contact adheres to the exterior side of the second layer **12**. This securing of the second layer onto itself provides a cocoon-like environment thereby allowing maximum surface contact of the inflated warming system with the patient. After enclosing the patient in the warming system, a heating device is attached to input port **22** to inflate the fluid flow passages formed between the first and second layer by the connecting points. Upon inflation, the inflated warming system conforms to the contours of the patient's body and provides increased surface contact of the first layer to the body. The reflective layer of the second layer encircles the patient and reduces heat loss due to thermal radiation. In this embodiment the patient is not placed on the inflated portion of the warming drape because the weight of the patient may reduce flow of the warming fluid as it traverses through the fluid flow passages.

Figure **11** illustrates a method of wrapping the patient in the warming drape embodiment of the present invention wherein the second layer extends beyond the portion of the drape that comprises both the first and second layer. The second layer **12** is positioned adjacent to the operating table. In operation, the patient's body is placed upon the warming

drape adjacent to the second layer **12** near the terminal end of the drape which has an adhesive means **28** thereon. The section of the warming drape on the opposite side of the patient is wrapped about the patient and then secured in place by adhering the adhesive means **28** to the second layer **12**. A coolant or heating fluid source is attached to input port **22** thereby transporting fluid through the system.

Figure **13** illustrates another embodiment of the present invention having three layers including a first layer **40** adjacent to the patient, a second outer layer **42** and a middle layer **44** positioned between the first and second layer. In this embodiment, the middle layer **44** and second layer **42** are attached to each other on their perimeters and at a plurality of connecting points **48** to form a plurality of air passages **46** for inflation when transporting a continuous stream of a warm gas therethrough. Additionally, the middle layer **44** is attached to the first layer **40** on their perimeters and at a plurality of connecting points **50** to form a plurality of liquid passages **52** for transporting a continuous stream of a warm liquid therethrough. Preferably, to provide optimal surface contact of the first layer with the patient's skin **38**, while in an inflated mode, there are more connecting points between the first layer **40** and middle layer **44** to minimize ballooning within the liquid passageways.

Upon inflation, surface contact of first layer **40** with the patient is increased when transporting the liquid through the liquid passageways which exerts an inward force against the patient. This inward pressure against the patient will be enhanced when the air passages are inflated causing greater contact of the first layer with the patient which provides more heat transference from the warm liquid through the first layer. Moreover, the inflated warming system, upon inflation of the air passageways, conforms to the patient's contours and provides enhanced transfer of thermal heat to the patient.

The increased pressure on the patient should not exceed the level of pressure that may occlude capillary flow or cause capillary damage to the patient. Preferably, the increased pressure on the patient should not exceed 1 psi, and more preferably it should not exceed 0.5 psi.

The three layers may be fabricated from any flexible, fluid impermeable material, such as a polymeric film which is sufficiently resilient to resist puncturing and includes those discussed above. The first layer and middle layer preferably has a thickness of from about 0.01 mil to about 2 mil and the second outer layer has a thickness of at least that of the first

and middle layer, and preferably, of a greater thickness.

This embodiment further comprises a reflective material which may be adhered to the first, second or middle layer and positioned to reflect thermal radiation escaping from the patient's body back to the patient. Preferably, the reflective layer is positioned on the second outer layer to reflect back to the patient any escaping thermal radiation. Any reflective material may be used including such materials as aluminum, silver, gold, copper, chromium or alloys thereof or other metal of sufficient density to reflect a significant portion of any thermal radiation incident thereon.

The three layers are secured to each other along their peripheral edges and at connecting points. Any appropriate fastening technique may be used, including, but not limited to sonic welding, laser welding, adhesive attachment, heat sealing, and a combination thereof. The connecting points may be placed randomly, arranged in even or offset rows throughout the warming blanket, in elongated seams that form tube-like passages or a combination thereof. The second and middle layer have less connecting points **48** than the amount of connecting points **50** between the middle and first layer. Preferably, the first and middle layer have at least twice as many connection points as the number of points between the middle and second layer. The connecting points are of a sufficient size to insure attachment but also provide sufficient space in the fluid flow passageways for easy transport of the temperature controlling fluid through the first and second interior chambers. The connecting points attaching the first and middle layer may be placed at approximately ½" to about 3" spatial intervals while the connecting points between the middle and second outer layer may be placed at about 1" to 6" intervals.

The temperature controlling fluid, whether it is gas or liquid, is introduced into the warming system at an input port or ports placed at any desired location or locations along the sealed peripheral edges or within the first and second layer. Output ports may also be placed accordingly. Any suitable input port fitting may be employed which may be adapted to fit most hose nozzles of standard warming or cooling units.

The external temperature controlling devices, whether introducing warm or cold gas or liquid, are separate heating or cooling units and may include units discussed above. Warm liquid introduced into the liquid passages formed between the first and middle layer should be maintained at a temperature that does not cause damage to the patient, and preferably the

temperature should not exceed 41°C, and more preferably, the temperature should be maintained at a temperature between 35° C to about 38°C. It should be noted that the temperature gradient between the warming fluid and the patient should not exceed a 10° C difference.

The temperature of the warming gas should be maintained at a temperature that may introduce additional heat to the patient and/or maintain a temperature gradient that forces the heat to remain in the body or at least a constant flow of heat towards the body. Thus understood, the temperature of the air in the outer chambers **46** should exceed the temperature of the liquid flowing through the inner chambers **52**.

Figure **16** illustrates a warming system of the present invention in a bunting type configuration. This embodiment provides for preserving and maintaining body heat when holding or moving a premature baby. The child is wrapped in the bunting which comprises at least a first **10** and second layer **12** of a flexible, fluid impermeable material that are sealed on their peripheral edges to form an interior chamber. At least the second layer has positioned thereon a reflective surface positioned to reflect escaping radiant heat back to the patient. The interior chamber has a plurality of connecting points **14** to form fluid flow passageways that directs the flow of a continuous stream of warm fluid through the warming bunting. In this embodiment at least one input port **22** facilitates the introduction of the continuous stream of a warm fluid into the interior chamber which may be directed to all parts of the bunting by the specific placement of the fluid flow passageways. This embodiment further provides for an attached hood **21** to warm the head of the enclosed child and reduce heat loss through the head. Upon inflation of the warming system, the first layer is forced against the child to conform to the contour's of his/her body. It should be recognized that the warming bunting may be constructed from the three layer embodiment wherein two different warming fluids are introduced to the warming system. Moreover, the bunting may be constructed so that the bottom edge of the bunting is sealed and the baby is slipped into the bunting.

Figures **17** and **18** provide illustrations for the preferred folding and method of placement of the warming drape shown in Figure **11**. Initially the drape is rolled or folded in a counter clockwise roll for packaging. The drape is unrolled and the portion of the drape comprising only the second layer is placed on the operating table. The patient is placed

directly on the second layer and the remaining portion of the drape, which is necessary to cover the patient, is unrolled and placed over the patient. Figure **18** shows the drape positioned adjacent to the skin of the patient **38** whereby the unused portion of the drape remains in a roll configuration. The second layer **12** is secured onto itself with attachment closure **28**.

Configurations of the present invention may include, a drape, a jacket model with a hood, individual structures that fit arms and legs or other parts of the torso, and a bag style constructed in several different sizes so that when inflated it snugly fits around the patient.

Any of the disclosed embodiments of the present invention may include an antimicrobial agent either directly incorporated into the flexible fluid impermeable material or coated thereupon. Additionally, the warming systems of the present invention may be sterilized by any method well known in the art that will not damage the warming system and then packaged accordingly.

What is claimed is:

1. A thermoregulation system for a patient characterized by comprising:

at least a first and second layer of flexible, fluid impermeable polymeric material joined at their perimeters to form at least one enclosed interior chamber, the first layer positioned adjacent to the patient;

a reflective surface positioned on at least the second layer to reflect escaping thermal radiation back to the patient;

at least one fluid flow passageway within the interior chamber defined by securing the first and second layer together at a plurality of connecting points within their perimeters; and

at least one input and output port connected to the interior chamber for transporting a continuous stream of a temperature controlling fluid through at least one fluid flow passageway.

2. The system according to claim 1 characterized in that the first layer comprises a metallized surface positioned to reflect escaping radiant heat back to the patient.

3. The system according to claim 1 characterized in that the output port directs exiting fluid away from the patient's body.

4. The system according to claim 1 characterized in that the first layer further comprises tubing passageways for transporting therethrough a continuous stream of a warming liquid.

5. The system according to claim 1 characterized in that the first layer further comprises resistive heating elements.

6. The system according to claim 1 characterized in that the temperature controlling fluid is a warm gas pumped at sufficient pressure to inflate the interior chamber to force the first layer against the patient.

7. The system according to claim 1 characterized in that the polymeric material of the second layer is of a greater thickness than the polymeric material of the first layer.

8. The system according to claim 1 characterized by further comprising an extension of the second layer that extends beyond the interior chamber formed by the first and second layer.

9. A warming system characterized by comprising multiple layers of a flexible, fluid impermeable material joined together to form a plurality of passageways for transporting

therethrough a continuous flow of at least one temperature controlling fluid thereby providing a source of conductive heat to the patient; and a reflective surface positioned on at least one of the layers to reflect escaping radiant heat back to the patient.

10. The warming system according to claim 9 characterized in that the multiple layers comprise a first layer that contacts a patient and second layer, the layer are joined at their perimeters and a plurality of connection points within their perimeters to form the plurality of passageways.

11. The warming system according to claim 9 characterized in that the temperature controlling fluid is a warm gas.

12. The warming system according to claim 10 characterized in that the reflective surface is positioned on the second layer.

13. A thermoregulation system for a patient characterized by comprising:

a first layer, a second layer and a middle layer positioned between the first and second layer, the first layer joined to the middle layer at their perimeters and at connection points within their perimeters to form a first interior chamber having at least one first fluid flow passageway, the second layer joined to the middle layer at their perimeters and at connection points within their perimeters to form a second interior chamber having at least one second fluid flow passageway, the first, second and third layer are fabricated from a flexible, fluid impermeable polymeric material;

at least one input and output port connected to the first interior chamber for transmitting a continuous flow of a temperature controlling fluid into and through the first interior chamber; and

at least one input and output port connected to the second interior chamber for transmitting a continuous flow of a temperature controlling fluid into and through the second interior chamber, the fluid flowing through the second interior chamber being different from the fluid flowing through the first interior chamber; and

a reflective surface positioned on at least the second layer to reflect thermal radiation back to the patient.

14. The system according to claim 13 characterized by further comprising an extension of the second layer extending beyond the first and second interior chambers formed by the first and middle layer and the middle and second layer.

15. The system according to claim 13 characterized in that the first interior chamber has a greater number of connection points than the number of connection points in the second interior chamber.

16. The system according to claim 13 characterized in that a warm gas is passed through the second interior chamber and a warm liquid is passed through the first interior chamber.

17. The system according to claim 16 characterized in that the polymeric material of the second layer is of a greater thickness than the polymeric material of the first layer.

18. The system according to claim 16 characterized in that the connection points between the first and middle layers are at least twice the number of connection points between the middle and second layers.

19. The system according to claim 16 characterized in that the system is of a bunting type configuration.

20. A method for restoring and maintaining normothermal temperatures in a patient, the method characterized by the steps comprising:

positioning a thermoregulation system according to claim 1 adjacent to the patient's body; and

inflating the system with a continuous stream of a temperature controlling fluid until the pressurized nature of the fluid within the passageways causes at least the first layer to conform to the patient's body; and

retaining the system in contact with the patient's body a sufficient time to restore and maintain normothermal temperatures.

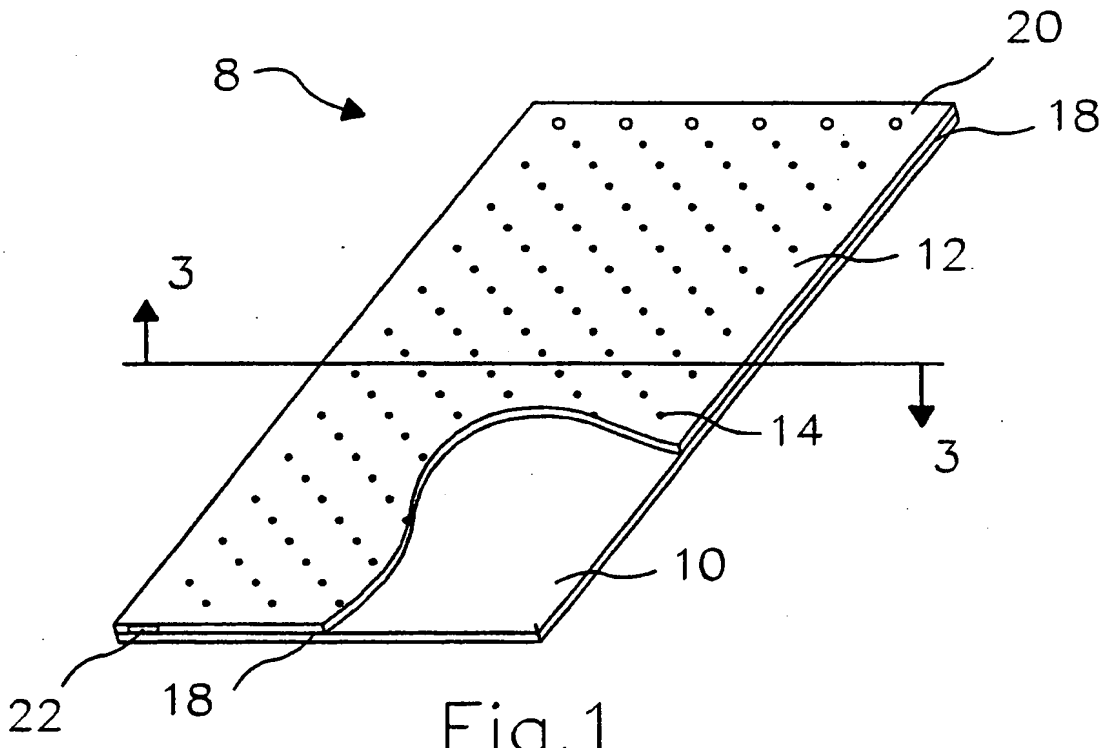

Fig.1

Fig.2

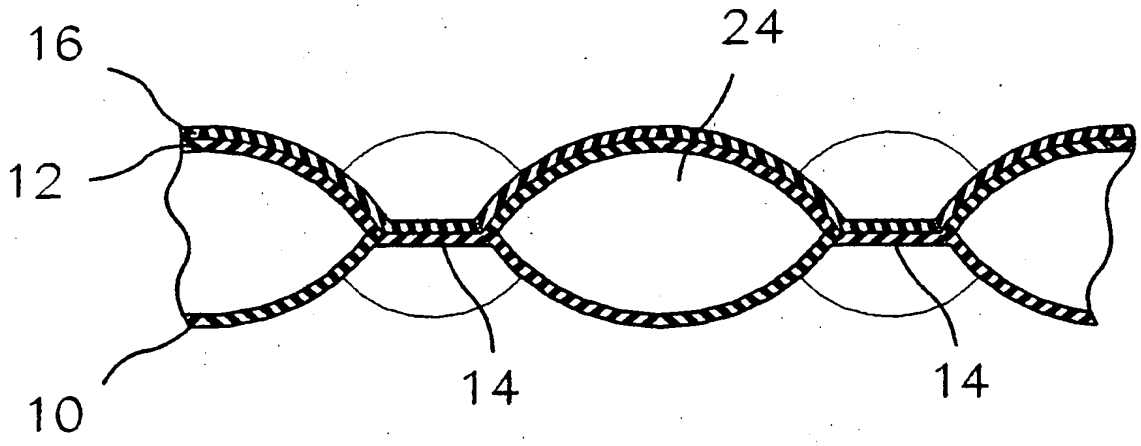

Fig. 3

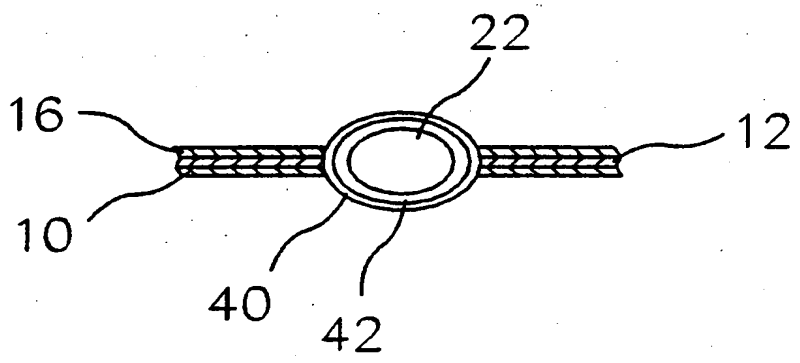

Fig. 4

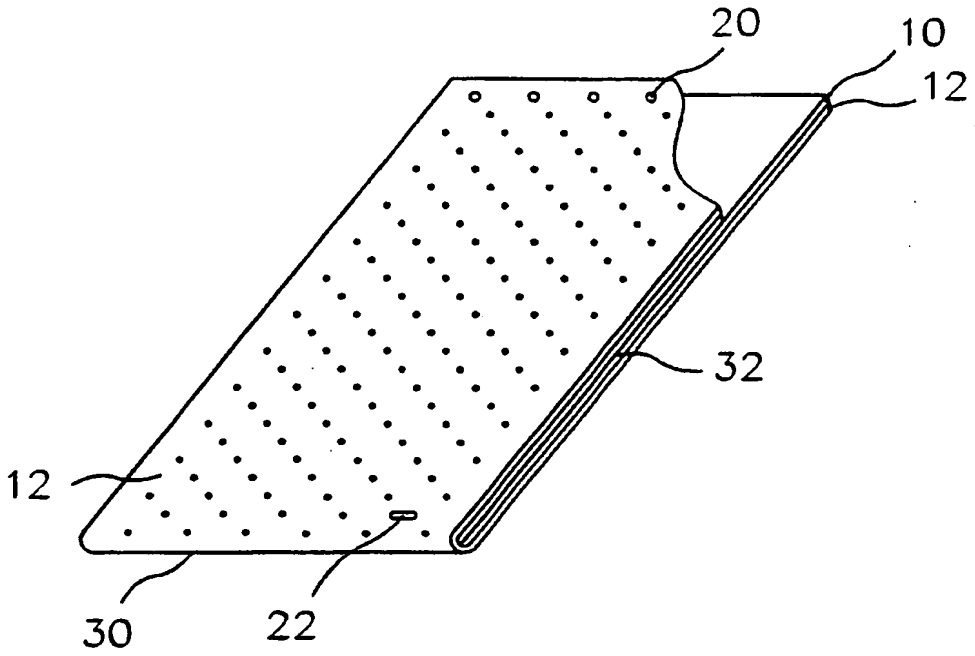

Fig.5

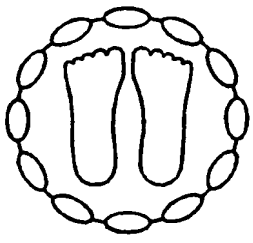

Fig.6

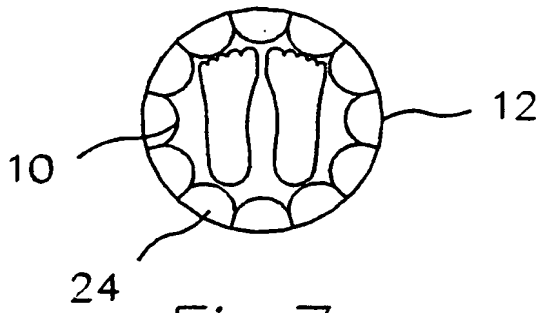

Fig.7

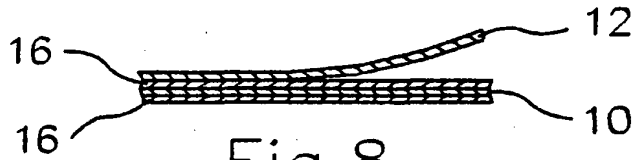

Fig.8

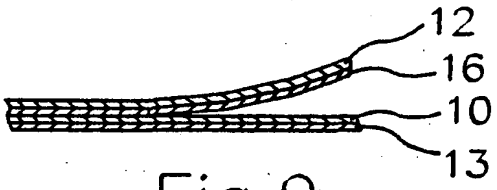

Fig.9

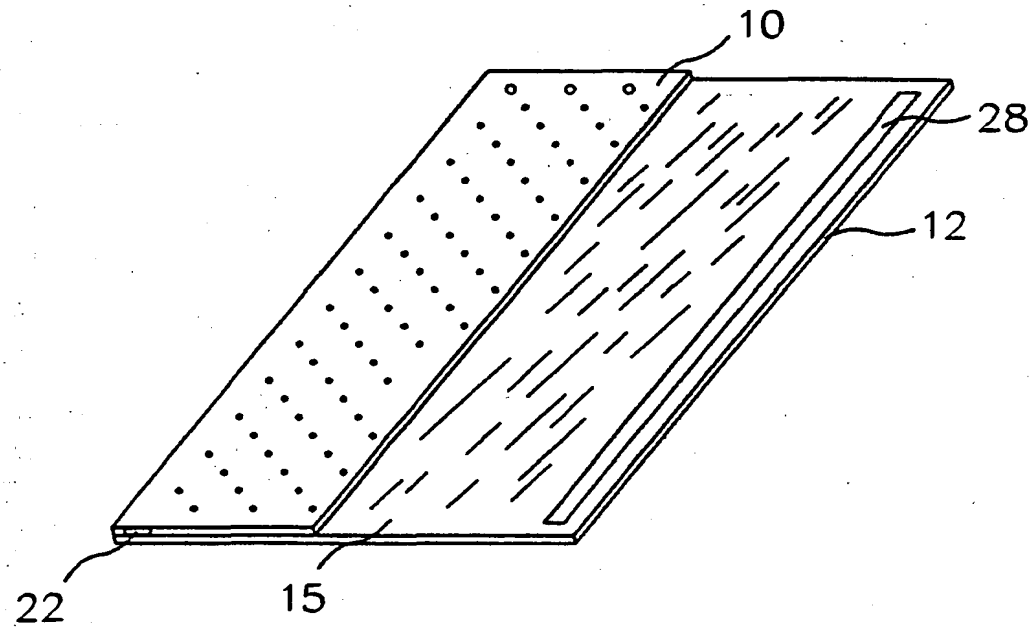

Fig.10

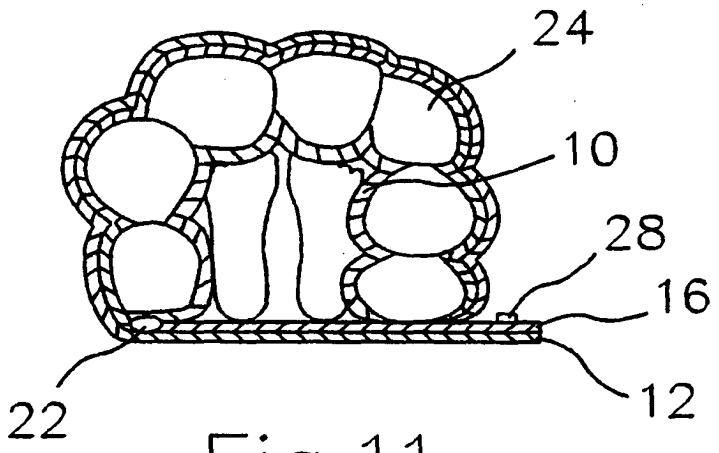

Fig.11

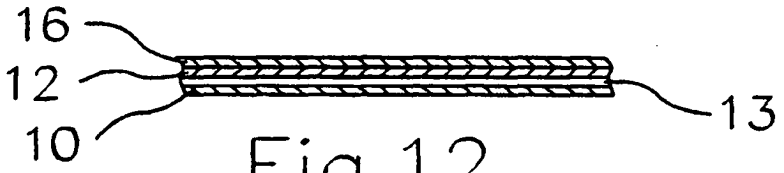

Fig.12

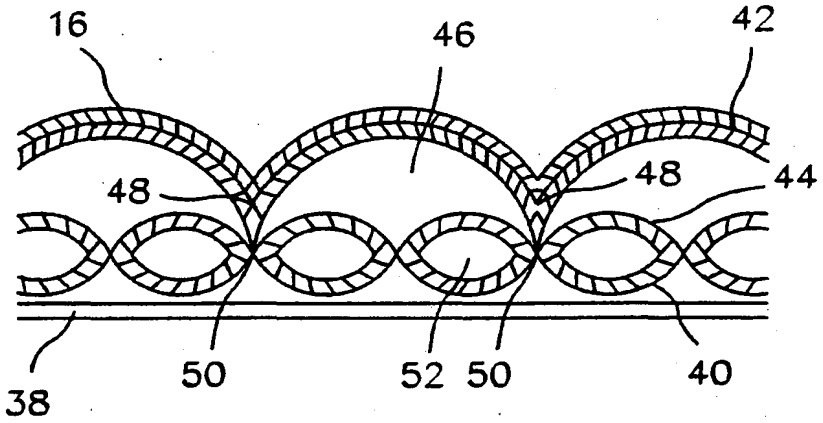

Fig.13

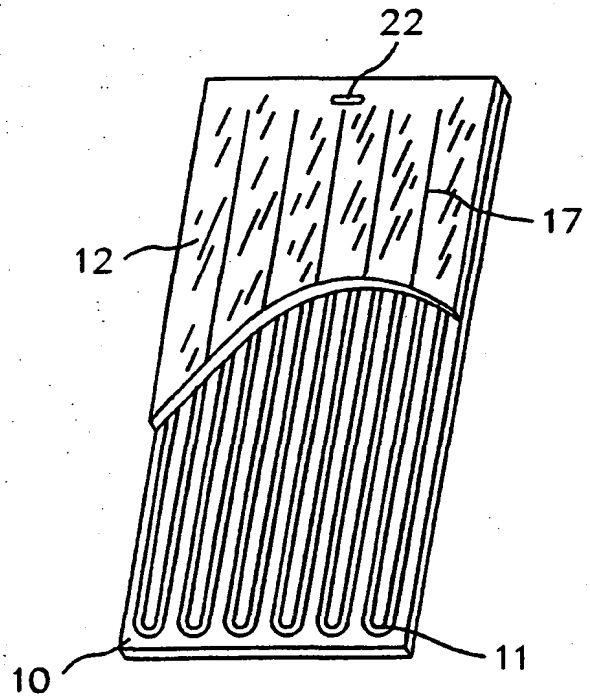

Fig.14

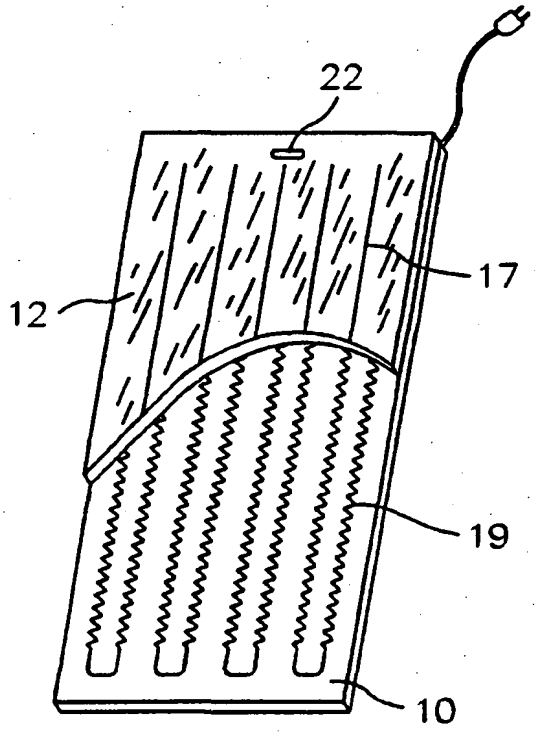

Fig.15

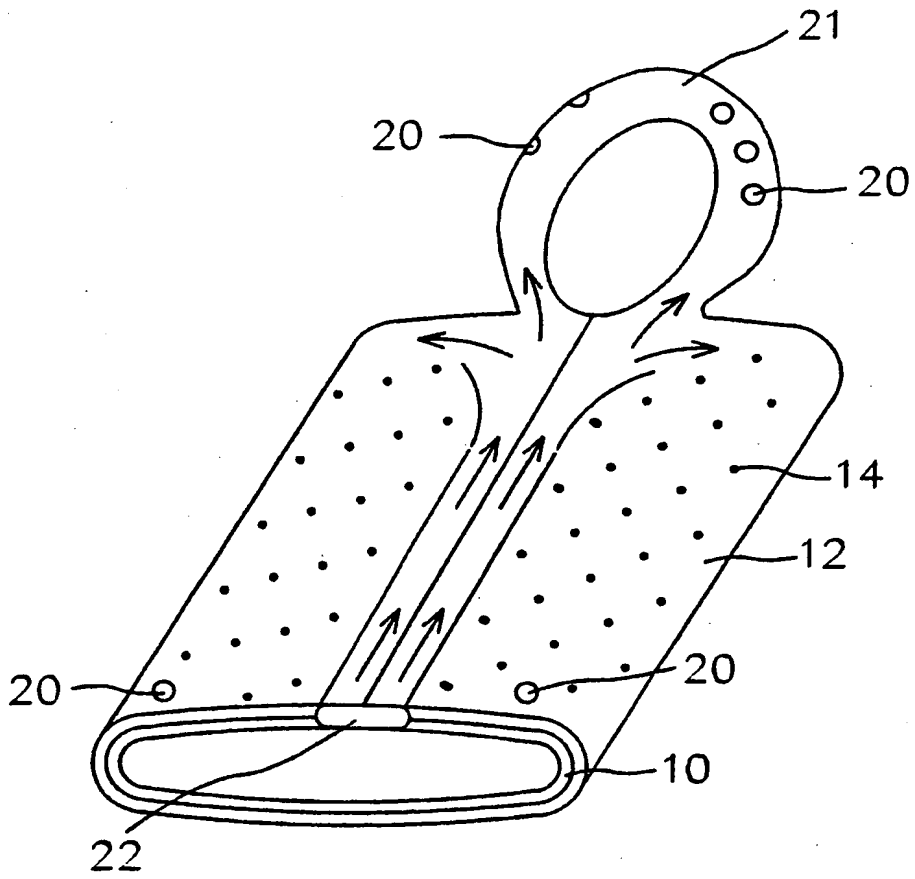

Fig.16

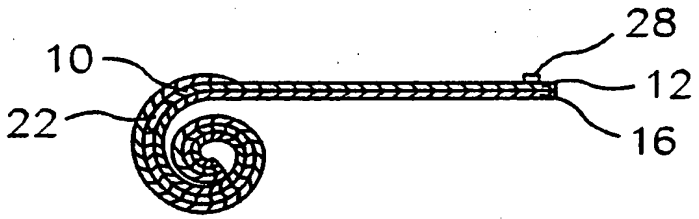

Fig.17

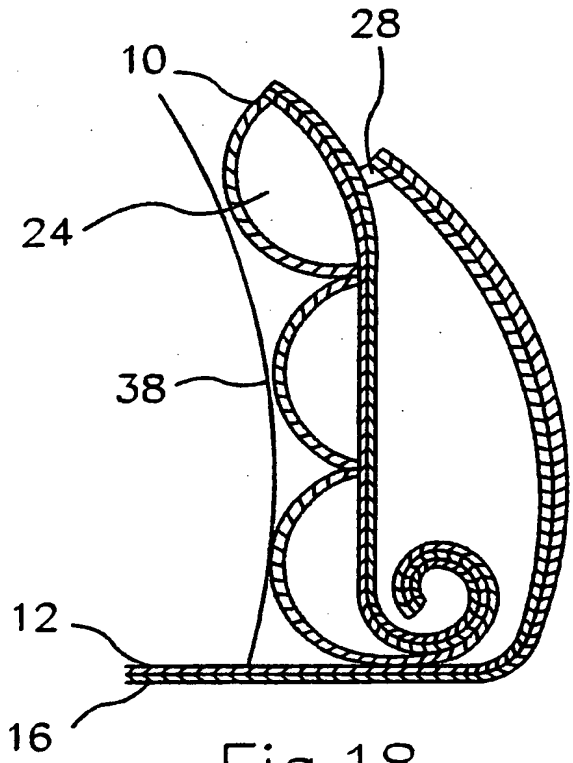

Fig.18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/13078

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 7/00
US CL : 607/104; 5/421, 655.3
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 607/104, 114, 107; 602/13, 14; 5/421, 422, 655.3, 668

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3,867,939 A (MOORE et al.) 25 February 1975 (25.02.1975), column 6, lines 14-36.	1-4, 6, 9-12
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Y		5, 7, 8, 13
Y	US 5,411,541 A (BELL et al.) 02 May 1995 (02.05.1995), col 5.	13-19
Y	US 5,835,983 A (MCMAHEN et al.) 10 November 1998 (10.11.1998).	5
Y	US 4,867,230 A (VOSS) 19 September 1989 (19.09.1989).	1, 9, 12, 13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"E" earlier application or patent published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 August 2000 (31.08.2000)	04 OCT 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LINDA DVORAK Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (July 1998)

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